

# Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in November 2014.

## Original Approvals

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This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

### NADA Number: 141-437

Trade Name: Osrurnia®  
Ingredients: Florfenicol, terbinafine, betamethasone acetate  
Sponsor: Novartis Animal Health US, Inc.  
Approval Date: November 4, 2014  
Status: Rx  
Route: Otic  
Species: Dogs  
Drug Form: Otic gel  
Concentration: 10 mg florfenicol, 10 mg terbinafine, and 1 mg betamethasone acetate per mL  
Indications: For the treatment of otitis externa in dogs associated with susceptible strains of bacteria (*Staphylococcus pseudintermedius*) and yeast (*Malassezia pachydermatis*).  
Exclusivity: 3 years  
Patent: Patent Number      Expiration date:  
6,887,487      October 31, 2022  
7,404,964      October 31, 2022  
7,618,651      July 10, 2027  
7,622,138      September 21, 2026  
7,846,472      November 19, 2026  
7,854,943      November 24, 2027  
7,858,115      February 23, 2027  
8,361,496      January 9, 2025

### ANADA Number: 200-510

Trade Name: Deracin®  
Pioneer: Aureomycin®  
Ingredients: Chlortetracycline  
Sponsor: Pharmgate LLC  
Approval Date: November 2, 2014  
Status: OTC  
Route: Oral, in feed  
Species: Cattle, swine, sheep, turkeys, chickens, ducks, and psittacine birds  
Drug Form: Type A medicated article  
Concentration: 50, 90, 100 g/lb  
Indications: **Calves (up to 250 lb):** Increased rate of weight gain and improved feed efficiency.  
**Calves (250-400 lb):** Increased rate of weight gain and improved feed efficiency.  
**Growing Cattle (over 400 lb):** Increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses.  
**Beef Cattle:** Control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.  
**Beef Cattle (under 700 lb):** Control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.  
**Beef Cattle (over 700 lb):** Control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.  
**Beef and Non-Lactating Dairy Cattle:** As an aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.  
**Calves, Beef, and Non-Lactating Dairy Cattle:** Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

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**Swine:** Control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.  
Treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.  
Increased rate of weight gain and improved feed efficiency.  
Reduction in incidence of cervical lymphadenitis (jowl abscesses) caused by Group E. *Streptococci* susceptible to chlortetracycline.  
**Breeding Swine:** Control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to chlortetracycline.  
**Turkeys:** Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.  
Increased rate of weight gain and improved feed efficiency.  
Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.  
Control of hexamitiasis caused by *Hexamita meleagridis* susceptible to Chlortetracycline.  
**Turkey poults not over 4 weeks of age:** Reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.  
**Sheep:** Increased rate of weight gain and improved feed efficiency.  
**Breeding Sheep:** Reduction in the incidence of (vibronic) abortions caused by *Campylobacter fetus* infection susceptible to chlortetracycline.  
**Ducks:** Control and treatment of fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline.  
**Chickens:** Increased rate of weight gain and improved feed efficiency.  
Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.  
Control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.  
Reduction of mortality due to *Escherichia coli* infections susceptible to chlortetracycline.  
**Psittacine birds (parrots, macaws, cockatoos):** Treatment of psittacine birds (parrots, macaws, cockatoos) suspected or known to be infected with psittacosis caused by *Chlamydia psittaci* sensitive to chlortetracycline.

### ANADA Number: 200-512

Trade Name:	Triamulox™
Pioneer:	Denagard® Liquid Concentrate
Ingredients:	Tiamulin hydrogen fumarate
Sponsor:	Zoetis Inc.
Approval Date:	November 7, 2014
Status:	OTC
Route:	Oral
Species:	Swine
Drug Form:	Concentrated liquid solution
Concentration:	Each mL of solution contains 123 mg (12.3%) tiamulin hydrogen fumarate
Indications:	Triamulox™, when administered in the drinking water for five consecutive days, is an effective antibiotic for the treatment of swine dysentery associated with <i>Brachyspira</i> (formerly <i>Serpulina</i> or <i>Treponema</i> ) <i>hyodysenteriae</i> susceptible to tiamulin at a dose level of 3.5 mg tiamulin hydrogen fumarate per pound of body weight daily and for treatment of swine pneumonia due to <i>Actinobacillus pleuropneumoniae</i> susceptible to tiamulin when given at 10.5 mg tiamulin hydrogen fumarate per pound of body weight daily.

### ANADA Number: 200-573

Trade Name:	Dexmedetomidine HCl
Pioneer:	Dexdomitor®
Ingredients:	Dexmedetomidine hydrochloride
Sponsor:	Putney, Inc.
Approval Date:	November 4, 2014
Status:	Rx
Route:	Dogs: IV or IM Cats: IM

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The following corrections or additions to the list were completed in November 2014.

Species: Dogs and cats  
Drug Form: Sterile Injectable Solution  
Concentration: 0.5 mg/mL  
Indications: For use as a sedative and analgesic in dogs and cats to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures. Dexmedetomidine HCl is also indicated for use as a preanesthetic to general anesthesia in dogs and cats.

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### Supplemental Approvals

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This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

#### **NADA Number: 034-267**

Trade Name: Gentocin® Durafilm®  
Ingredients: Gentamicin sulfate, betamethasone  
Sponsor: Intervet, Inc.  
Approval Date: November 10, 2014

This supplement provides for a new product formulation.

#### **NADA Number: 141-349**

Trade Name: Draxxin® 25 Injectable Solution  
Ingredients: Tulathromycin  
Sponsor: Zoetis Inc.  
Approval Date: November 19, 2014

This supplement provides for use in suckling calves, dairy calves, and veal calves for the treatment of BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*.